

THE NEED AND PROSPECTS FOR NEW AND IMPROVED VACCINES

Many infectious diseases are still major causes of death, disease, and disability in the United States and worldwide. The reemergence of familiar diseases once thought controlled, such as tuberculosis and malaria, and the emergence of new diseases, such as HIV/AIDS and Lyme disease, show that infectious diseases will continue to threaten the public health (Centers for Disease Control and Prevention, 1993; excerpts from this document are included here in appendix 4). These diseases already result in great suffering and significant health care costs. Thus the need for new and improved vaccines is clear. Therefore research directed toward developing new and improved vaccines is being supported by the National Institutes of Health, the Department of Defense, the U.S. Agency for International Development (USAID), States with vaccine production facilities, and vaccine companies,

The National Institute of Allergy and Infectious Diseases (NIAID) reports annually on progress being made toward new and improved vaccines for more than 50 disease-causing agents, as well as on other aspects of vaccinology, such as adjuvant development, clinical trials methodology, and combination vaccines. As reported in "The Jordan Report: Accelerated Development of Vaccines -- 1993," more than 150 new or improved vaccine candidates are in various stages of basic research, animal testing, or human testing. For 25 diseases, vaccine candidates (sometimes more than one) have reached clinical trials (see figure 3). In recent years, the Public Health Service has been particularly active in the evaluation of new pertussis vaccine candidates. In addition, the urgent need for a vaccine to help in controlling the rapidly growing AIDS pandemic has been actively addressed by NIH, in particular the NIAID Division of AIDS, and the Department of Defense. A wide range of approaches to a vaccine to prevent HIV infection are being pursued through basic research, animal testing or phase I and II clinical trials. Preparation of sites for phase III trials is underway.

As of December 1993, Product License Applications had been submitted to the Food Drug Administration (FDA) for vaccines against hepatitis A and varicella. Vaccines in phase III clinical trials (for efficacy) include those for rotavirus diarrhea, pertussis (improved), cholera (improved), pneumococcal otitis media, typhoid (improved), leprosy, malaria, leishmaniasis, and various viral encephalitic fevers, representing potential candidates for licensure if efficacious and safe.

In March 1993, NIAID convened a panel of experts to advise it on long-term goals for vaccine research and recommend priorities for the use of anticipated additional resources for FY 1993 and FY 1994. The conclusions of that group, outlined in the report "NIAID Blue Ribbon Panel on Vaccine Research: Summary" (National Institute of Allergy and Infectious Diseases, 1993), will guide NIAID in executing its responsibilities under the overall strategic plan described in this document (the summary is reproduced here in appendix 6). NIAID is in the process of preparing "critical path" development plans for all major (non-HIV/AIDS) vaccine candidates. Research priorities and development strategies for HIV/AIDS vaccines are contained in the "NIAID HIV/AIDS Research Agenda" (National Institute of Allergy and Infectious Diseases, 1993c).

USAID reports annually on its vaccine development and immunization activities in "Child Survival: Report to Congress on the USAID Program." With regard to international vaccine research and development priorities, the CVI Task Force on Strategic Planning identified 12 infectious agents for which new and improved vaccines would address a large disease burden and could be available in the next 5 years. Although some of these also represent NIAID priorities, others (such as a heat-stable polio vaccine or specific formulations of pneumococcal vaccines) would be used mostly outside the United States. The CVI is attempting to catalyze research, development, and testing of these vaccines.

CHANGING PRIVATE-SECTOR INVOLVEMENT IN VACCINE INNOVATION

Apart from some limited-volume manufacturing capacity in State facilities (Massachusetts and Michigan) and the pilot lot facilities of the Department of Defense, the United States is reliant upon private-sector production for its vaccine supply, whether for widely used vaccines or for those used in particular